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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,335	09/28/2000	Joseph M. Cummins	5523-67250	7680

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EXAMINER
BELYAVSKYI, MICHAIL A

ART UNIT	PAPER NUMBER
1644	8

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/672,335	CUMMINS ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *1-23 and 29-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892) ✓
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 3/4/03 (Paper No. 7), is acknowledged.

Claims 1-39 are pending.

Claims 1-23 and 29-39 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 24-28 are under consideration in the instant application.

2. The following new ground of rejection are necessitated by the amendment filed 3/4/03 (Paper No. 7),

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummins (US Patent NO: 5,019,382) in view of Fleischmann et al. (Proc. Soc. Exp. Biol. Med. 1992, 201 (12) 200-207)

US Patent '382 teaches an anti-inflammatory pharmaceutical formulation, comprising a low dosage from about 1 to about 15,000 IU of human interferon and a pharmaceutically acceptable carrier. (see entire document, Abstract , column 2, line 65 and column 13, line 46 in particular). US Patent '382 teaches that interferon is a term generically comprehending a group of vertebrate glycoproteins and proteins which are known to have various biological activities (

column 1, lines 15-20 in particular). US Patent '382 teaches that interferon of type I group i.e. IFN-alpha and IFN-beta as well as and type II ,i.e. IFN-gamma can be used (see column 3, lines 20-45 in particular). Cummins also teach that said pharmaceutical formulation can be in liquid or solid form (column 13, lines 40-65) , or saliva-soluble form (see Abstract in particular) or formulation in lozenge dosage form (column 13, lines 20-40). Cummins teaches that said pharmaceutical formulation can be useful for treatment of neoplastic disease, hyperallergenicity, autoimmune disorders characterized by chronic tissue degenerative inflammation and immuno-resistant viral infections , infectious disease of viral origin in human, canine and feline species (see Abstract and Claim 1 in particular).

US Patent '382 does not explicitly teaches that a pharmaceutical formulation, comprising a low dosage from about 10 to about 50,000 IU of human IFN-gamma or oral administration of human IFN-gamma.

Fleischmann et al. teach a method of oral administration of INF-alpha, INF-beta and INF-gamma (see entire document, Abstract in particular). Fleischmann et al. further teach that oral administration of interferon is a new route of administration that is very beneficial (see abstract in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Fleischmann et al., to those of US Patent '382 to obtain a claimed an anti-inflammatory pharmaceutical formulation comprising unit dosage form for oral administration.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because oral administration of IFN-gamma can be a new rout of administration of interferon, as taught by Fleischmann et al. that can be used for an anti-inflammatory pharmaceutical formulation taught by US Patent '382 .

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The claimed dosage from about 10 to about 50,000 IU of human IFN-gamma overlaps the referenced low dosage from about 1 to about 15,000 IU of human IFN-gamma and is therefore an obvious variation of the reference teaching absent a showing of unobvious property. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

Applicant's arguments, filed 3/4/03, Paper NO: 7 have been fully considered, but have not been found convincing.

Applicant asserts that US Patent '382 describes use of only IFN-beta and IFN- alpha and that oral dosage formulation would not have been obvious to the skilled practitioner at the time the invention was made.

Contrary to Applicants assertion, as has been discussed supra, US Patent '382 describes use of low dose formulation of IFN-gamma and from the combined teaching of US Patent '382 and Fleischmann et al. oral dosage formulation would have been obvious to a person of ordinary skill in the art at the time the invention was made.

5. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cummins (US Patent NO: 5,019,382) in view of Fleischmann et al. as applied to claims 24-27 above, and further in view of Schlom et al., (US Patent NO; 6,045,802) or Goeth et al., (US Patent NO: 5,178,857).

The teaching of US Patent '382 and Fleischmann et al. have been discussed, supra.

US Patent '382 and Fleischmann et al. do not teach a pharmaceutical formulation comprising of human IFN-gamma and a therapeutic agent selected from a group consisting of an antibiotic, an antifungal, an antifibrotic and a chemotherapeutic agent known for use in cancer therapy or for treatment of immune diseases characterized by hypoactive or hyperactive immune system dysfunction.

Schlom et al., teach a combination therapy, wherein a pharmaceutical composition comprises combination of INF-gamma and immunomodulators or immunostimulators, chemotherapeutic drugs, antibiotics, antifungal drugs and antiviral drugs (see entire document, column 13, line 9-25 in particular) and pharmaceutically acceptable carrier.

Similarly, Goeth et al., teach combine therapy, wherein a pharmaceutical composition comprises combination of INF-gamma and antibiotics (see entire document, Abstract in particular). Goeth et al., also teach that combine therapy is more efficient than monotherapy using INF gamma alone (column 4, line 45-50 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Schlom et al., or Goeth et al., to those of US Patent '382 and Fleischmann et al. to obtain a claimed a pharmaceutical formulation for oral administration comprising of human IFN-gamma and a therapeutic agent selected from a group consisting of an antibiotic, an antifungal, and a chemotherapeutic agent known for use in cancer therapy or for treatment of immune diseases characterized by hypoactive or hyperactive immune system dysfunction.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because combination therapy, wherein a pharmaceutical composition comprises combination of INF-gamma and immunomodulators or immunostimulators, chemotherapeutic drugs, antibiotics, antifungal drugs and antiviral drugs and pharmaceutically acceptable carrier is more efficient than monotherapy using INF gamma alone as taught by Schlom et al., or Goeth et al.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments, filed 3/4/03, Paper NO: 7 have been fully considered, but have not been found convincing.

Applicant asserts that US Patent '382 describes use of only IFN-beta and IFN- alpha and that oral dosage formulation would not have been obvious to the skilled practitioner at the time the invention was made.

As has been discussed, supra it is the Examiner position that US Patent '382 describes use of low dose formulation of IFN-gamma and from the combined teaching of US Patent '382 and Fleischmann et al. oral dosage formulation would have been obvious to a person of ordinary skill in the art at the time the invention was made.

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
April 21, 2003.